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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,585

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Larry Lapanashvili

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EXAMINER

LAVERT, NICOLE F

ART UNIT

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4123

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,585	Applicant(s) LAPANASHVILI ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 25-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/02/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 18-24, drawn to an electrotherapy apparatus.

Group 2, claim(s) 25-31, drawn to an electrotherapy apparatus.

Group 3, claim(s) 32-37, drawn to a method of treating a person or a mammal.

2. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- a. Claim 18 is drawn to an electrotherapy apparatus comprising a sensor, a processor, and a trigger system. All of which are known in the art at the time of the invention, as demonstrated below.
- b. Claim 25 is drawn to an electrotherapy apparatus comprising a sensor, a processor, a trigger system and a plurality of channels for applying electrical stimulation. All of which are known in the art at the time of the invention.
- c. Claim 32 is drawn to a method of treating a person or a mammal using an electrotherapy apparatus, providing each plurality of channels with a time delay. All of which are known in the art at the time of the invention.

There is a clear lack of unity of invention because the common matter of the independent claims is well known and the remain subject matter of each claim differs from that of the others without there being any unifying novel inventive concept.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. During a telephone conversation with Babak Kusha on December 14, 2007 a provisional election was made without indication of traverse to prosecute the invention of 10/578585, claims 18-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because a) reference character "34" has been used to designate both the display and the electrocardiogram [(pp 19, para 3) & (pp 20, para 1)]. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if

only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: The "...dotted lines..." represented by the reference number 98, is not shown (pp 33, para 2). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because a) the notation "LYP," should be changed to "LVP," (Figure 3), b) In respect to the section notated by "B" the reference numbers "98'" and "94'" should be changed to "98'" and "94'," respectfully (Figure 3). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

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sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase “Not Applicable” should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.

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- (1) Field of the Invention.
- (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The disclosure is objected to because of the following informalities: a) The status of the foreign application number WO 2001/13990A must be updated (pp 1, para 2), b) In respect to the phrase, "...in the curve 88..." the reference number "88" should be changed to "90," (pp 30, para 4), c) In respect to the phrase, "...into the computer 36..." the reference number "36" should be changed to "100," (pp 33, para 2), d) the specification lacks the headings discussed and required above. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 1, the phrase "for example" in line 2 renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 18-24** are rejected under 35 U.S.C. 102(b) as being anticipated by Lapanashvili et al. (WO 01/13990).

For **claim 18**, Lapanashvili et al. discloses, an electrotherapy apparatus comprising a sensor for detecting periodically recurring signal peaks, for example the R-R peaks of an electrocardiogram of a person, a processor for deriving from said periodically recurring signal peaks a time delay corresponding to approximately the end of the T-wave, a trigger system or a circuit initiated by an output signal of said processor or embodied within said processor for applying electrical stimulations to one or more active electrodes provided on the said person at a time related to the end of said time delay [(pp 3, para 4) & (pp 25, para 2-5)], the processor being adapted: a) to make a determination for successive pairs of signal peaks of a value corresponding to the time between said successive pairs of signal peaks and thus to the said person's heart rate (pp 19, para 4), b) to compare said value with maximum and minimum permissible technical limits permitted by the apparatus and/or c) to compare said value with

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maximum and minimum permissible selected limits, (pp 14, para 2) d) to determine whether each said value exceeds a preceding value or a preceding value averaged over a plurality of heart beats by more than a defined amount, e) to determine whether each said value is less than a preceding value or a preceding value averaged over a plurality of heart beats by more than a defined amount [(pp 41, para 5) & (pp 42, para 1-4)], f) to trigger said trigger system or circuit (pp 25, para 3-5) only when the comparisons b) and/or c) are favourable and the determinations d) and e) show that the said value does not exceed the preceding value or the preceding average value by more than the defined amount and is not less than the preceding value or the preceding value by more than the defined amount [(pp 41, para 5) & (pp 42, para 1-4)], g) to close a measurement window for said sensor (pp 60, para 2) once a determination is made that the comparisons b) and/or c) are favourable and that the determinations d) and e) show that the said value does not exceed the preceding value or the preceding average value by more than the defined amount and is not less than the preceding value or the preceding average value by more than the defined amount [(pp 41, para 5) & (pp 42, para 1-4)], said measurement window being closed prior to triggering said trigger system [(pp 60, para 1-2) & (pp 61, para 1)], h) to calculate in addition to said time delay a maximum stimulation length [(pp 61, para 4) & (pp 61, para 1)], i) to check that the derived value of said time delay is greater than or equal to a delay time equivalent to a trigger delay plus a calculation delay [(pp 61, para 4) & (pp 61, para 1)], said trigger delay being the delay between initiation of a trigger signal delivered by said sensor corresponding to the detection of a first signal peak and the time this signal reaches the

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processor (pp 25, para 2-5) and the calculation delay being the time required by the processor to derive the delay [(pp 61, para 4) & (pp 62, para 1)], j) to check that the derived time delay is less than or equal to said maximum stimulation length [(pp 61, para 4) & (pp 61, para 1)], and to revise said derived time delay if necessary so that [(pp 25, para 4-5) & (pp 61, para 4) it fulfills the two conditions derived time delay greater than or equal to the trigger delay plus the calculation delay and derived time delay less than or equal to the maximum stimulation length [(pp 61, para 4) & (pp 61, para 1)], k) to calculate a maximum duration equal to the maximum stimulation length minus the time delay [(pp 62, para 4), (pp 63, para 4) & (pp 64, para 3)] l) to calculate a duration of said electrical stimulation and a maximum duration value equal to said maximum stimulation length minus said derived time delay [(pp 62, para 4), (pp 63, para 4) & (pp 64, para 3)] and to check whether said calculated duration is less than or equal to said maximum duration and if not to adapt it so that it is less than or equal to said maximum duration [(pp 63, para 2-3) & (pp 64, para 4)], m) to calculate an open measurement window time equal to said derived time delay, or said adapted delay, if said delay has been adapted [(pp 61, para 1-4) & (pp 63, para 3)], plus said duration or said adapted duration, if said duration has been adapted [(pp 62, para 4) & (pp 63, para 3)], plus a safety margin (pp 63, para 5), and n) to send an output signal to said trigger system during said measurement window and open said measurement window at the calculated time permitting the recognition of the detection of a further peak of said electrocardiogram by said sensor [(pp 60, para 1-2) & (pp 61, para 1-2)].

In reference to **claim 19**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 18 (pp 3, para 4), wherein said processor is adapted to repeat the sequence of steps based on the new R-R value (pp 25, para 1-3).

In reference to **claim 20**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 19 (pp 3, para 4), wherein, if a further signal peak is not detected after opening of said measurement window within an expected time calculated by said processor based on a preceding value or a preceding average value, no trigger signal is transmitted and transmission of a trigger signal and thus stimulation is inhibited until further signal peaks are detected within expected limits (pp 59-pp 61, para 1-2).

In reference to **claim 21**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 18 (pp 3, para 4), wherein, instead of using a value of the preceding time between signal peaks as said value, an average is formed from a plurality of past values (pp 63, para 4).

In reference to **claim 22**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 21 (pp 3, para 4), wherein the processor is adapted to include in said plurality of past values only those values which lie within a range less than the preceding measured value plus a predefined positive deviation and more than a value corresponding to the preceding measured value less a predefined deviation [(pp 61, para 4) & (pp 62, para 1-3)].

In reference to **claim 23**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 18 (pp 3, para 4), wherein the apparatus has a

plurality of channels for applying electrical stimulations to one or more active electrodes provided on the said person and in that for each said channel [(pp 16, para 2) & (pp 24, para 4)] a respective offset value is added to said delay (pp 62, para 1-2).

In reference to **claim 24**, Lapanashvili et al. discloses, an electrotherapy apparatus in accordance with claim 21 (pp 3, para 4), wherein the apparatus has a plurality of channels for applying electrical stimulations to one or more active electrodes provided on the said person and in that for each said channel [(pp 16, para 2) & (pp 24, para 4)] a respective offset value is added to said delay (pp 62, para 1-2).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EP1078649.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N.F.L.

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123